

PATENT

AMENDMENTS TO THE CLAIMS

Following is a complete set of claims as amended with this Response. This complete set of claims includes amended claims 1 and 19 and new claims 38-40.

1. (Currently Amended) An implantable stimulation lead system, comprising:
a lead including a lead body dimensioned for placement inside the coronary sinus region, the lead body having at least one electrode positioned at a distal end of the lead body, the distal end of the lead body including a distal tip, the lead further having a lumen extending the length of the lead and communicating with an aperture in the distal tip; and
a device dimensioned for insertion within the lumen, the device including:
a main body;
a steering knob secured to a proximal extremity of the main body;
and
a flexible distal portion secured to a distal extremity of the main body, the main body having a length such that, with the main body of the device substantially completely advanced within the lead, the flexible distal portion of the device projects distally from the aperture in the distal tip of the lead body;
wherein a combined length of the main body of the device and the flexible distal portion of the device is slightly longer than the lead body.
2. (Withdrawn) The lead system defined in claim 1 in which:
the main body and the flexible distal portion of said device comprise a unitary structure.
3. (Original) The lead system defined in claim 1 in which:
the main body and flexible distal portion of said device comprise separate structures joined at the distal extremity of the main body.

PATENT

4. (Original) The lead system defined in claim 1 in which:
the main body is formed of wire.
5. (Original) The lead system defined in claim 4 in which:
the flexible distal portion of the device comprises a wire coil.
6. (Withdrawn) The lead system defined in claim 5 in which:
the wire coil comprising the flexible distal portion of the device has an
outer diameter equal to that of the main body.
7. (Original) The lead system defined in claim 5 in which:
the wire coil comprising the flexible distal portion of the device has an
outer diameter smaller than that of the main body.
8. (Withdrawn) The lead system defined in claim 4 in which:
the flexible distal portion of said device comprises a proximal section and
a distal section, the distal section being more flexible than the proximal section.
9. (Withdrawn) The lead system defined in claim 8 in which:
the proximal section and the distal section of the distal portion of the
device comprise wire coils.
10. (Withdrawn) The lead system defined in claim 9 in which:
the wire coil comprising the distal section has an outer diameter smaller
than that of the wire coil comprising the proximal section.
11. (Withdrawn) The lead system defined in claim 10 in which:
the wire coil comprising the proximal section has an outer diameter
substantially the same as that of the main body.

PATENT

12. (Withdrawn) The lead system defined in claim 10 in which:
the wire coil comprising the proximal section has an outer diameter smaller than that of the main body.
13. (Withdrawn) The lead system defined in claim 8 in which:
the proximal and distal sections comprise a unitary structure.
14. (Withdrawn) The lead system defined in claim 13 in which:
the proximal and distal sections are cylindrical, the proximal section having an outer diameter smaller than that of the main body and the distal section having an outer diameter smaller than that of the proximal section.
15. (Withdrawn) The lead system defined in claim 13 in which:
the proximal section is cylindrical and has a diameter smaller than that of the main body, and wherein the distal section comprises a thin leaf.
16. (Withdrawn) The lead system defined in claim 15 in which:
the thin leaf has a rectangular shape, the leaf having a width equal to the diameter of the proximal section.
17. (Withdrawn) The lead system defined in claim 16 in which:
the flexible distal portion of the device includes a wire coil surrounding the proximal and distal sections of the flexible distal portion.
18. (Withdrawn) The lead system defined in claim 17 in which:
the thin leaf includes a distal tip, the wire coil surrounding the proximal and distal sections of the flexible distal portion having an end attached to the distal tip of the thin leaf and another end attached to the distal extremity of the main body.

PATENT

19. (Currently Amended) ~~A device for delivering a body implantable lead, the device~~ An implantable stimulation lead system, comprising:

a lead comprising:

a lead body dimensioned for placement inside the coronary sinus region;

a tip electrode having an aperture, the tip electrode disposed at a distal end of the lead body; and

a lumen extending a length of the lead body and communicating with the aperture in the tip electrode; and

a device dimensioned for insertion within the lumen, the device

comprising:

a main wire body having a proximal extremity and a distal extremity;

a steering knob secured to the proximal extremity of the main wire body; and

a flexible distal portion having a proximal end secured to the distal extremity of the main wire body, the flexible distal portion comprising a wire coil;

wherein a combined length of the main wire body of the device and the flexible distal portion of the device is slightly longer than the lead body such that, with the main wire body of the device substantially completely advanced within the lead body, the flexible distal portion of the device projects distally from the aperture of the tip electrode.

20. (Withdrawn) The device defined in claim 19 in which:

the wire coil comprising the flexible distal portion of the device has an outer diameter substantially the same as that of the main body.

PATENT

21. (Original) The device defined in claim 19 in which:
the wire coil comprising the flexible distal portion of the device has an outer diameter smaller than that of the main body.
22. (Withdrawn) The device defined in claim 19 in which:
the wire coil comprising the flexible distal portion of said device includes a proximal section and a distal section, the distal section being more flexible than the proximal section.
23. (Withdrawn) The device defined in claim 22 in which:
the distal section of the wire coil has an outer diameter smaller than that of the proximal section of the wire coil.
24. (Withdrawn) The device defined in claim 23 in which:
the proximal section of the wire coil has an outer diameter substantially equal to that of the main body.
25. (Withdrawn) The device defined in claim 23 in which:
the proximal section of the wire coil has an outer diameter smaller than that of the main body.
26. (Withdrawn) A device for delivering a body implantable lead, the device comprising:
a main wire body having a proximal extremity and a distal extremity;
a steering knob secured to the proximal extremity of the main wire body;
and
a flexible distal portion having a proximal end secured to the distal extremity of the main body, the flexible distal portion of said device comprising a proximal section and a distal section, the distal section being more flexible than the proximal section.

PATENT

27. (Withdrawn) The device defined in claim 26 in which:
the proximal section and the distal section of the flexible distal portion of
the device comprise wire coils.
28. (Withdrawn) The device defined in claim 27 in which:
the wire coil comprising the distal section has an outer diameter smaller
than that of the wire coil comprising the proximal section.
29. (Withdrawn) The device defined in claim 28 in which:
the wire coil comprising the proximal section has an outer diameter
substantially the same as that of the main body.
30. (Withdrawn) The device defined in claim 28 in which:
the wire coil comprising the proximal section has an outer diameter
smaller than that of the main body.
31. (Withdrawn) The device defined in claim 26 in which:
the proximal and distal sections comprise a unitary structure.
32. (Withdrawn) The device defined in claim 31 in which:
the proximal and distal sections are cylindrical, the proximal section having an
outer diameter smaller than that of the main body and the distal section having an outer
diameter smaller than that of the proximal section.
33. (Withdrawn) The device defined in claim 31 in which:
the proximal section is cylindrical and has a diameter smaller than that of the
main body, and wherein the distal section comprises a thin leaf.

PATENT

34. (Withdrawn) The device defined in claim 33 in which:
the thin leaf has a rectangular shape with a width substantially the same as the diameter of the proximal section.
35. (Withdrawn) The device defined in claim 34 in which:
the flexible distal portion of the device includes a wire coil surrounding the proximal and distal sections of the flexible distal portion.
36. (Withdrawn) The device defined in claim 35 in which:
the thin leaf includes a distal tip, the wire coil surrounding the proximal and distal sections of the flexible distal portion having one end attached to the distal tip of the thin leaf and another end attached to the proximal end of the flexible distal portion.
37. (Withdrawn) A method of implanting an electrode of an endocardial lead at an implantation site within a cardiac vein accessible via the superior vena cava (SVC), coronary os and the coronary sinus region, the lead including a distal portion and a lumen communicating with an aperture in a tip electrode, said implanting being effected using a device comprising a main body, a steering knob secured to a proximal extremity of the main body and a flexible distal portion affixed to and extending distally from a distal extremity of the main body, the method comprising the steps of:
inserting the device into the lumen of the lead with the flexible distal portion substantially entirely contained within the distal portion of the lead;
feeding an introducer sheath along a predetermined path including at least the SVC and coronary os;
inserting the distal portion of the lead into the introducer sheath and advancing the lead until the distal portion of lead reaches the coronary sinus region;
advancing the device relative to the lead to extend the flexible distal portion of the device from the aperture in the tip electrode;

PATENT

manipulating the steering knob on the proximal end of the main body of the device as necessary to maneuver the flexible distal portion of the device into said implantation site;

slidably advancing the lead over the device to move said electrode into place at the implantation site;

retracting the device and removing the device from the lead; and
retracting and removing the introducer sheath.

38. (New) The lead system defined in claim 1, wherein the at least one electrode is a distal tip electrode.

39. (New) The lead system defined in claim 1, wherein the combined length of the main body and flexible distal portion is about 5 to 15 cm longer than the lead body.

40. (New) The lead system defined in claim 19, wherein the combined length of the main wire body of the device and the flexible distal portion of the device is about 5 to 15 cm longer than the lead body.